

91. The method of claim 90, wherein said placing step comprises placing the distal end of the shaft in a patient's body so that the distal tip of the distal end is disposed adjacent and distal to target tissue.

REMARKS

Claims 1 and 49-91 are in the application, including new claims 68-91 added in this amendment. Support for the amendments to claims 1, 53, 55, 58, and 65 and for the new claims may be found throughout the application and figures as originally filed at, for example, page 17, lines 9-14, and in Figure 15. No new matter is added by way of these amendments and added claims.

Claims 1 and 49-52 stand rejected under 35 USC §102(a) as being anticipated by Saadat (WO 98/24372) and claims 55-57 stand rejected under 35 USC §102(a) as being anticipated by Imran (WO 94/27670). Claims 53, 54, and 58-67 stand rejected under 35 USC §103(a) as being obvious over Saadat in view of Imran. Applicants respectfully traverse the rejections.

The Rejection of Claims 1 and 49-52 under 35 U.S.C. §102(a)

Claims 1 and 49-52 stand rejected under 35 USC §102(a) as being anticipated by Saadat (WO 98/24372). Anticipation under 35 USC §102 requires that "every element of the claimed invention be identically shown in a single reference" (*In re Bond*, 910 F.2d 831, 832 (Fed. Cir. 1990)). However, Saadat does not discuss a distal cutting element, nor, in particular, a distal cutting element disposed on a shaft distal tip. Unlike the present invention, Saadat discusses devices having fixation elements disposed on their distal tips (see, e.g., Figs. 3A, 3B, 7, and 8).

Accordingly, lacking at least these elements of the claimed invention, applicants respectfully submit that Saadat fails to anticipate claims 1 and 49-52.

Th Rejection of Claims 55-57 under 35 U.S.C. §102(a)

Claims 55-57 stand rejected under 35 USC §102(a) as being anticipated by Imran (WO 94/27670). As mentioned above, anticipation under 35 USC §102 requires that "every element of the claimed invention be identically shown in a single reference" (*In re Bond*, 910 F.2d 831, 832 (Fed. Cir. 1990). Imran does not discuss placing a shaft in body tissue within a patient's body; nor, in particular, does Imran discuss placing a shaft of a device having a distal cutting element disposed on a shaft distal tip in body tissue within a patient's body. Unlike the present invention, Imran discusses a device having fixation elements disposed on its distal tip (see, e.g., Figs. 2-5).

Accordingly, lacking at least these elements of the claimed invention, applicants respectfully submit that Imran fails to anticipate claims 55-57.

The Rejection of Claims 53, 54, and 58-67 under 35 U.S.C. §103(a)

Claims 53, 54, and 58-67 stand rejected under 35 USC §103(a) as being obvious over Saadat in view of Imran. In order to establish a prima facie case of obviousness, the prior art references must teach or suggest all the claim limitations; there must be some suggestion or motivation, in the references or in the knowledge generally available to one of ordinary skill in the art, to modify or combine reference teachings; and there must be a reasonable expectation of success were the teachings to be so modified or combined. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

However, as discussed above, Saadat fails to discuss a distal cutting element, and particularly, a distal cutting element disposed on the distal tip of the shaft. Imran does not discuss placing a shaft in body tissue within target tissue of a patient's body; nor, in particular, does Imran discuss placing a shaft of a device having a distal cutting

element disposed on the distal tip of a shaft to access target tissue within a patient's body. In particular, neither cited reference discusses devices or methods having a shaft with a distal cutting element disposed on a shaft distal tip.

Neither Saadat nor Imran contains any suggestion or motivation to provide these missing elements, such as a distal cutting element, nor any suggestion or motivation to be combined with the other reference to provide the missing elements. Moreover, both Saadat and Imran teach away from the present invention, discussing devices having fixation elements located at the distal tips. Such fixation elements in Saadat and Imran would interfere with, or make impossible the placement and function of a distal cutting element as required by the present invention. Lacking any suggestion or motivation to be combined to provide the missing distal cutting element, the cited references fail to provide any reasonable expectation of success for such a combination.

Accordingly, lacking at least these elements of the claimed invention, the combination of Saadat in view of Imran fails to make claims 53, 54, and 58-67 obvious.

The New Claims

The new claims added in this amendment include, among other elements, a side-cutting element configured for cutting a tissue specimen from the target tissue and methods directed to the use of devices including such a side-cutting element. Applicants note that neither Saadat nor Imran discuss a side-cutting element configured for cutting a tissue specimen, nor devices having cutting elements configured for cutting a tissue specimen.

Applicants believe that the present claims define patentable subject matter and respectfully request reconsideration and an early allowance thereof.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. A medical device for localization of target tissue comprising:

a shaft having a distal end, a proximal end defining a proximal direction, and a side, said distal end having a distal tip, said shaft being configured for placement of said distal end into a patient's body tissue at a desired location;

a distal cutting element disposed on said distal tip; and

a fixation element ^{exposed portion} which has a free end and which is disposed on said distal end proximal of said distal tip, [said fixation element being] and configured for ^{penetration} securing the distal end of said medical device adjacent target tissue at said desired location.

112

non-attached
to the shaft
member

55. A method of performing a medical procedure, comprising:
- a) [using] providing a medical device comprising a shaft having a distal end with a tip, a proximal end, a fixation element which has a free end and which is spaced proximal to the distal tip, a distal cutting element disposed on said distal tip, [and a longitudinal axis defining a radial direction generally perpendicular to said axis,] comprising:
- a) placing the distal end of the shaft in body tissue within a patient's body, so that the distal end is disposed [adjacent] within target tissue; and
- b) extending into the target tissue [a] the free end of the fixation element from a side of the shaft spaced proximal to the distal [end] tip, [said member having a free end configured for engaging tissue,] so that the distal end of the shaft becomes secured [adjacent] within the target tissue.

58. A method of performing a medical procedure using a medical device comprising a shaft having a distal end with a distal tip, a distal-cutting element disposed on said distal tip, a proximal end, a fixation element which has a free end and which, [and a longitudinal axis defining a radial direction generally perpendicular to said axis], comprising:

- a) cutting through tissue of a patient's body with said distal cutting element;
- b) placing the distal end of the shaft in body tissue within a patient's body, so that the distal end is disposed adjacent target tissue; and
- c) extending into the target tissue a fixation element from a side of the shaft spaced proximal to the distal end, said member having a free end configured for engaging tissue, so that the distal end of the shaft becomes secured adjacent the target tissue.

65. A method for acquiring a tissue specimen from target tissue using a tissue acquisition device having a shaft with a distal end with a distal tip, a proximal end, a distal cutting element disposed on said distal tip, a fixation element having a free end, [and a longitudinal axis defining a radial direction generally perpendicular to the axis]; comprising:

- a) placing the distal end of the shaft in target tissue within a patient's body, so that the distal [end] tip is disposed distally adjacent the target tissue;
- b) securing the distal end of the shaft [adjacent] within the target tissue by extending into the target tissue [a] the free end of the fixation element [from a side of the shaft spaced proximal to the distal end, said fixation element having a free end] configured for engaging tissue; and
- c) acquiring [one or more] a tissue [samples] specimen of target tissue.